

AMENDMENT

IN THE CLAIMS

Please amend the claims as indicated in Appendix A submitted herewith according to the revision to 37 C.F.R. § 1.121 concerning a manner for making claim amendments.

REMARKS

Claims 1-3 are presently pending in the captioned application with claims 1-3 being amended by the present amendment.

Claims 1-3 have been amended to contain the limitation of extracting cartilage with a solution of acetic acid of 4% or more as well as being amended to overcome various indefiniteness rejections. Support for the limitation of an acetic acid solution of 4% or more can be found in the specification at page 5, line 21.

No new matter within the meaning of § 132 has been included by the amendment.

Accordingly, Applicants respectfully request the Examiner to enter the amendment and reconsider and allow all claims pending in this application.

1. Rejection of Claims 1-3
under 35 U.S.C. § 112, ¶ 2

The Office Action rejects claims 1-3 under 35 U.S.C. § 112, ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Office Action states:

Claim 1 is indefinite because the claim lacks essential steps in the method of extraction of crude proteoglycan. The omitted step is the step of extracting cartilage to obtain crude proteoglycan. Claim 1 is also indefinite as to what acid and what concentration of the acid used for extracting.

Claims 2 and 3 are indefinite because the claims recite using acetic acid as eluting solvent of cartilage, but it does not indicate what concentration of acetic acid is used for extracting, e.g., is it 100%, 50%, 10% or 4% acetic acid is used in the process.

Claim 3 is indefinite because the use of the term "further improving the purity of crude proteoglycan". The term "further improving the purity of crude proteoglycan" renders the claim indefinite, it is not clear what procedure is referred to for improving the purity of crude proteoglycan.

Applicants respectfully traverse the rejection because the claims have now been amended to overcome the various rejections. In particular, claim 1 has been amended to include a step of extracting cartilage to obtain crude proteoglycan. Claims 2 and 3 have been amended to include the concentration of acetic acid used

for extracting the crude proteoglycan. Claim 3 has further been amended to clarify that a method of preparing crude proteoglycan is being claimed rather a method of "further improving the purity of crude proteoglycan."

Applicants would like to take this opportunity to point out that the Office Action only makes prior art rejections against claim 1 even though independent claim 2 and 3 are also pending in the application. Presumably, the only outstanding rejections against claims 2 and 3 are under § 112, ¶2.

Accordingly, Applicants respectfully submit that the presently claimed invention particularly points out and distinctly claims the subject matter of the invention and respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, ¶ 2.

2. Rejection of Claim 1
under 35 U.S.C. § 102(b)

The Office Action rejects claim 1 under 35 U.S.C. § 102(b) as being anticipated by Biochemistry 11, 4903-4909 (1972) ("Miller et al."). The Office Action states:

Miller et al. teach a method for preparing collagen, where the proteoglycan components are removed from the fresh cartilage slices by first extraction with 0.05 M Tris, 1.0 M NaCl, pH 7.5, and then extracting with 0.5 M acetic

acid (page 4904, left column, paragraph 4;
claim 1).

Applicants respectfully traverse the rejection over Miller et al. because each and every claimed limitation of presently pending independent claim 1 is not taught. In particular, Miller et al. does not teach the limitation of extracting cartilage with a solution of acetic acid of 4% or more. Any inherency analysis is prohibited in a § 102(b) anticipation rejection insofar as the concentration of the acid is specifically limited to 0.5M acetic acid.

Turning to the rule, the Federal Circuit has spoken clearly and at some length on the question of anticipation. Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Those elements must be expressly disclosed as in the claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990).

The prior art reference must also be enabling, thereby placing the allegedly disclosed matter in the possession of the public. In re Brown, 329 F.2d 1006, 1011, 241 USPQ 245, 249 (C.C.P.A. 1964). In order to accomplish this, the reference must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which

it pertains could construct and use it. Id. at 250.

Finally, the Federal Circuit has made clear that a negative pregnant is not enough to show anticipation. Rowe v. Dror, 112 F.3d 473, 42 USPQ2d 1550 (Fed. Cir. 1997). Thus, where a reference does not explicitly describe anything inconsistent with a claimed use, if that reference nevertheless fails to make an affirmative suggestion of the claimed limitations, that reference cannot anticipate the claimed use. Id.

In the present application, representative claim 1 recites a method of preparing crude proteoglycan comprising the step of extracting cartilage with a solution of acetic acid of 4% or more to obtain crude proteoglycan. Nowhere does Miller et al. teach the presently claimed solution of acetic acid of 4% or more, which is a 0.667M solution. Although Miller et al. teaches a 0.5M solution, Applicants note that a solution of 0.667M solution is quite different than the disclosed 0.5M solution of Miller et al. The presently claimed 0.667M solution of the present invention has unexpected results.

Accordingly, Applicants respectfully submit that the presently claimed invention is not anticipated by Miller et al. and respectfully request the Examiner to reconsider and withdraw the § 102(b) rejection.

3. Rejection of Claim 1
under 35 U.S.C. § 102(e)

The Office Action rejects claim 1 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 2001/0016646 ("Rueger et al."). The Office Action states:

Rueger et al. teach proteoglycans are extracted from lyophilized cartilage and tissue sections by treating with 4 M guanidine HCl, 0.15 M potassium acetate at pH 5.8 in the presence of proteinase inhibitor at 4°C for 60 hours (paragraph 0418; claim 1). Since the claim does not identify the acid used for extraction, the acidic solution (pH 5.8) containing potassium acetate meets the criteria of claim 1.

Applicants respectfully traverse the rejection over Rueger et al. because each and every claimed limitation of presently pending independent claim 1 is not taught. In particular, Rueger et al. does not teach the limitation of extracting cartilage with a solution of acetic acid of 4% or more. Any inherency analysis is prohibited in a § 102(b) anticipation rejection insofar as the concentration of the acid taught by Rueger et al. is specifically limited to 0.15 M potassium acetate at pH 5.8.

Turning to the rule, the Federal Circuit has spoken clearly and at some length on the question of anticipation. Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. Verdegaal Bros. v.

Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Those elements must be expressly disclosed as in the claim. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990).

The prior art reference must also be enabling, thereby placing the allegedly disclosed matter in the possession of the public. In re Brown, 329 F.2d 1006, 1011, 241 USPQ 245, 249 (C.C.P.A. 1964). In order to accomplish this, the reference must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it pertains could construct and use it. Id. at 250.

Finally, the Federal Circuit has made clear that a negative pregnant is not enough to show anticipation. Rowe v. Dror, 112 F.3d 473, 42 USPQ2d 1550 (Fed. Cir. 1997). Thus, where a reference does not explicitly describe anything inconsistent with a claimed use, if that reference nevertheless fails to make an affirmative suggestion of the claimed limitations, that reference cannot anticipate the claimed use. Id.

In the present application, representative claim 1 recites a method of preparing crude proteoglycan comprising the step of extracting cartilage with a solution of acetic acid of 4% or more to obtain crude proteoglycan. Nowhere does Rueger et al. teach the presently claimed solution of acetic acid of 4% or more. Although Rueger et al. teaches 0.15 M potassium acetate at pH 5.8 in the

presence of proteinase inhibitor at 4°C for 60 hours, Applicants note that the presently claimed 0.667M acetic acid solution is not anticipated by the 0.15 M potassium acetate acidic solution of Rueger et al. Notably, the presently claimed 0.667M solution of the present invention has unexpected results.

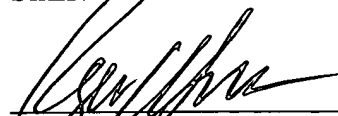
Accordingly, Applicants respectfully submit that the presently claimed invention is not anticipated by Reuger et al. and respectfully request the Examiner to reconsider and withdraw the § 102(b) rejection.

CONCLUSION

In light of the foregoing, Applicants submit that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims. Favorable action with an early allowance of the claims pending is earnestly solicited.

Respectfully submitted,

SHERMAN AND SHALLOWAY



Attorney for Applicants
Roger C. Hahn
Reg. No. 46,376

SHERMAN AND SHALLOWAY
413 N. Washington Street
Alexandria, Virginia 22314
703-549-2282



Attorney Docket No. TAN-291
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Group Art Unit: 1653
TAKAGAKI) Examiner: Chih Min KAM
Serial No. 09/916,250)
Filed: July 30, 2001)

For: **METHOD FOR EXTRACTION AND PURIFICATION OF
CARTILAGE TYPE PROTEOGLYCAN**

Appendix A

Please amend the following claims as indicated according to the revision to 37 C.F.R. § 1.121 concerning a manner for making claim amendments.

1. (Currently amended) A method for ~~extraction~~ preparation of crude proteoglycan ~~characterizing to use acid as eluting solvent of cartilage~~ comprising extracting cartilage with a solution of acetic acid of 4% or more to obtain crude proteoglycan.

2. (Currently amended) A method for ~~extraction~~ preparation of crude proteoglycan comprising + :

~~extracting crude proteoglycan using acetic acid as eluting solvent of cartilage~~ cartilage with a solution of acetic acid of 4% or more,

filtrating the solution ~~containing crude proteoglycan~~
obtained by said extracting to remove dregs from said solution,

centrifuging the solution obtained by said filtrating,

adding ethanol saturated with sodium chloride to the supernatant liquid obtained by said centrifuging,

and then centrifuging said supernatant liquid ~~added with~~ said ethanol saturated with sodium chloride to concentrate said crude proteoglycan in the precipitate form precipitate
containing crude proteoglycan.

3. (Currently amended) A method for ~~further improving the~~
purity preparation of crude proteoglycan comprising:

~~extracting crude proteoglycan using acetic acid as eluting solvent of cartilage,~~ cartilage with a solution of acetic acid of 4% or more,

filtrating the solution ~~containing crude proteoglycan~~
obtained by said extracting to remove dregs from said solution,

centrifuging the solution obtained by said filtrating,

adding ethanol saturated with sodium chloride to the supernatant liquid obtained by said centrifuging,

centrifuging said supernatant liquid ~~added~~ with said ethanol saturated with sodium chloride to ~~concentrate said crude proteoglycan in the preeipitate~~ form precipitate containing crude proteoglycan,

dissolving said precipitate containing crude proteoglycan ~~using acetic acid as eluting solvent of said crude proteoglycan~~ in a solution of acetic acid,

and then ~~dialysising~~ dialyzing the solution.